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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,890	04/17/2002	Michael Noel Kiernan	UDL-115	1536
7590	03/11/2005		EXAMINER	
GORDON & JACOBSON, P.C. 65 WOODS END ROAD STAMFORD, CT 06905			JOHNSON III, HENRY M	
			ART UNIT	PAPER NUMBER
			3739	
			DATE MAILED: 03/11/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/980,890	KIERNAN ET AL.
Examiner	Art Unit	
Henry M Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 August 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18,20-23 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-18,20-23 and 25-27 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 04 December 2001 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

### ***Response to Arguments***

Applicant's arguments filed August 25, 2004 have been fully considered but they are not persuasive. When the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, a case-by-case determination must be made as to anticipation. If the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. The applicant has not provided conclusive proof of unexpected results and did not mention unexpected results in the original disclosure. The examples provide no documentation of sample size so as to produce evidence of a statistically significant result. Further, one test used a wide variance of pulse duration and energy density making the selection of one particular variable as critical impossible.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 10-12, 17 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No.

6,443,946 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are an obvious change in scope.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7-12, 14-15, 17, 20-23, 25 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,443,946 B2 to Clement et al. Clement discloses a method and apparatus for wrinkle removal by irradiation with narrow (15nm) bandwidth radiation in the range of 570 to 600 nm or 750 to 850 nm (Col. 3, lines 27-28), with an energy density of 0.5 to 5 J/cm<sup>2</sup> per pulse (Col. 3, line 32) and a pulse duration in the range of 200 µs to 1 ms (Col. 5, line 21) and with spot sizes from 1 to 10 mm (Col. 5, line 34). The device may have lenses and filters through which the radiation passes as it is directed to a target thus implying these elements are external to the area to be treated (Col. 6, line 13-20). The energy is controlled (Col. 5, line 43) so as not to exceed 5 J/cm<sup>2</sup>. The wavelength is selected to match the absorption of the target chromophore (Col. 2, line 61). The radiation source may be an LED or semiconductor laser (Col. 6, line 12). Clement discloses the effects of exposure to include generation of new collagen (Col. 2, line 13).

Regarding claim 20, blood vessels are present in both the basal and dermis layers thus the treatment is directed at veins and arteries.

Regarding claim 22, the irradiating unit has a focusing means (Col. 5, line 32) and emitter (Fig. 7, #112).

Regarding claim 23, the irradiating means is interpreted as being inherently configured in a handpiece for manual manipulation.

Claims 1, 2, 4, 7, 8-11, 14, 20-27 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/24512 to Jones et al. Jones discloses an apparatus for stimulating collagen with a laser radiation source at wavelengths of 585 nm and 694 nm (Page 7, lines 1-4) and means for directing the radiation to a target site, external to the site (Fig. 3 and page 5, paragraph 4). The 585 nm wavelength is disclosed for vascular (veins and arteries) treatment (Page 7, line 3). The directing means may be motor controlled. Jones teaches a focusing means (page 8, lines 10-15). The radiation has a pulse duration of from 200  $\mu$ s to 1 ms (Page 6, paragraph 6). A scanning means is disclosed (Page 8, lines 10-16). Control of the irradiation to prevent injury and pain is disclosed (Page 4, lines 5-8).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,443,946 B2 to Clément et al as applied to claim 1 above, and further in view of U.S. Patent 6,156,028 to Prescott. Clement is discussed above, but does not disclose use with an

internal delivery means. Prescott teaches a method for increased collagen deposition using radiation (Col. 2, lines 30-31) that may be delivered via a catheter inserted into a body (abstract), thus bypassing extraneous tissue. Vertical cavity surface emitting lasers are delivered to the treatment area via the catheter (Col. 5, line 64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a catheter to deliver the radiation as taught by Prescott in the invention of Clement to focus the treatment radiation directly on an internal target.

Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,443,946 B2 to Clement et al as applied to claim 1 above, and further in view of U.S. Patent 5,964,749 to Eckhouse et al. Clement is discussed above, but does not disclose a broadband white light source. Eckhouse discloses a method and apparatus for wrinkle smoothing by increasing the elasticity of the collagen (Col. 3, line 25) that employs pulsed radiation at from 600 to 1200 nm. The radiation is produced by a flashlamp with a filter system to cut off the unwanted radiation (Col. 4, lines 4-6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the flashlamp source as taught by Eckhouse in the invention of Clement as a well known alternative source of the treatment radiation.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Henry M. Johnson, III  
Patent Examiner  
Art Unit 3739

  
ROY D. GIBSON  
PRIMARY EXAMINER